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McCormick et al
U.S. Serial No. 09/522,900
Page 2 of 13**AMENDMENTS TO THE CLAIMS:**

This listing of claims will replace all prior versions and listing of the claims in the application:

LISTING OF THE CLAIMS:

Claim 1. (currently amended) A purified polypeptide self-antigen, useful as a B-cell lymphoma tumor specific ~~vaccine~~ antigen in a subject with a B-cell lymphoma tumor or at risk of developing the B-cell lymphoma tumor, encoded by a nucleic acid comprising a nucleic acid sequence found in cells of said tumor that encodes an idiotypic part of a surface immunoglobulin epitope, which polypeptide:

- (a) has an amino acid sequence containing a surface immunoglobulin idiotypic epitope or epitopes unique to, or overexpressed by, cells of said tumor, thereby distinguishing said tumor from all other tumors (i) of the same or different histological type, (ii) in said subject or in another member of said subject's species;
- (b) is produced in a cell or organism that has been transformed or transfected with a nucleic acid encoding a peptide sequence having the same peptide sequence or sequences as said surface immunoglobulin epitope or epitopes encoded by said nucleic acid in the cells of said tumor of said subject;
- (c) is obtainable from said cell or organism in correctly folded form, without a need for denaturation and renaturation and mimics said surface immunoglobulin epitope or epitopes in their native form;
- (d) induces an immune response in a mammal, including said subject, when administered said polypeptide without a need for an adjuvant or other immunostimulatory materials, so that administration of said polypeptide results in an antibody or cell-mediated immune response to said surface immunoglobulin epitope or epitopes.

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Claim 2. (previously presented) The polypeptide of claim 1 wherein the cell or organism is a plant or a plant cell.

Claim 3. (previously presented) The polypeptide of claim 2 which is transiently produced in said transformed or transfected plant or plant cell.

Claim 4. (previously presented) The polypeptide of claim 2 which comprises at least two peptide domains.

Claim 5. (canceled)

Claim 6. (previously presented) The polypeptide of claim 1 that includes at least one idiotypic epitope of the V region of said immunoglobulins.

Claim 7. (previously presented) The polypeptide of claim 6 that comprising two V region domains of said immunoglobulin

Claim 8. (previously presented) The polypeptide of claim 7 wherein said two domains are at least part of the V_H and at least part of the V_L domains of said immunoglobulin.

Claim 9. (previously presented) The polypeptide of claim 8 wherein said part of the V_H region includes at least one complementarity-determining region (CDR).

Claim 10. (previously presented) The polypeptide of claim 9 wherein said CDR of said polypeptide is CDR2.

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Claim 11. (previously presented) The polypeptide of claim 8 that is a two-domain single-chain antibody (scFv) that includes said at least part of the V_H and V_L domains.

Claim 12. (previously presented) The polypeptide of claim 11 that includes said V_H and V_L domains.

Claim 13. (previously presented) The polypeptide of claim 12 wherein said domains of said polypeptides are linked by an amino acid linker that

- (a) has between one and about 50 residues;
- (b) consists of between one and 12 different amino acids, and
- (c) facilitates secretion and correct folding of said polypeptide to mimic the tumor epitope in its native form in or on said tumor cell.

Claim 14. (previously presented) The polypeptide of claim 13 wherein the linker is a member of a randomized library of linkers that vary in size and sequence, and said library is encoded by nucleic acid sequences consisting of a repeated pattern of degenerate repeated triplet nucleotides having the following requirements;

- (i) position 1 of each repeated triplet cannot be the same nucleotide as position 2 or the repeated triplet;
- (ii) position 2 of each repeated triplet cannot be the same nucleotide as position 3 of the repeated triplet; or
- (iii) position 1 of each repeated triplet cannot be the same nucleotide as position 3 of the repeated triplet.

Claim 15. (previously presented) The polypeptide of claim 14, wherein the nucleotide in the first and second positions of each repeated triplet is selected from two of deoxyadenosine, deoxyguanosine, deoxycytidine or deoxythymidine.

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Claim 16. (previously presented) The polypeptide of claim 15,
wherein

- (i) position 1 of each repeated triplet is deoxyadenosine or deoxyguanosine;
 - (ii) position 2 of each repeated triplet is deoxycytidine or deoxyguanosine;
- and
- (iii) position 3 of each repeated triplet is deoxythymidine.

Claim 17. (previously presented) The polypeptide of any one of claims
3, or 11-16 in solution.

Claim 18. (previously presented) The polypeptide of any one of claims
3, or 11-16 adsorbed to, bound to, or integrated into, a carrier or delivery system.

Claim 19. (previously presented) The polypeptide of any one of claims
3, or 11-16, wherein said immune response is a protective anti-tumor immune response.

Claim 20. (previously presented) The polypeptide of any one of claims
3, or 11-16 that, upon administration to a mammalian host, including said subject, said
polypeptide induces a polyclonal anti-idiotypic antibody response or a cell mediated
immune response.

Claim 21. (previously presented) The polypeptide of claim 20 wherein
the host is a human and said polyclonal anti-idiotypic responses are detected by testing
serum or peripheral blood cells of the host.

Claim 22. (previously presented) The polypeptide of claim 20 wherein
the antibody response is measured by an enzyme immunoassay or by flow cytometry.

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Claim 23. (previously presented) The polypeptide of claim 20 wherein said administration comprises subcutaneous immunization with at least about 15µg of said polypeptide three times each about two weeks apart.

Claims 24-28 (canceled).

Claim 29. (currently amended) A ~~vaccine~~ composition useful for inducing a tumor-specific immune response, comprising

- (a) the polypeptide of any one of claims 3 or 11-16; and
- (b) a pharmaceutically acceptable carrier or excipient.

Claims 30-36 (canceled).

Claim 37. (currently amended) The ~~vaccine~~ composition of claim 29, further comprising an adjuvant.

Claim 38. (currently amended) The ~~vaccine~~ composition of claim 29, further comprising an immunostimulatory cytokine or a chemokine.

Claim 39. (currently amended) The ~~vaccine~~ composition of claim 38, wherein said cytokine is selected from the group consisting of interleukin 1, interleukin 2, interleukin 12, interleukin 18, and interferon-γ.

Claim 40. (currently amended) The ~~vaccine~~ composition of claim 29 in unit dosage form wherein said excipient is sterile saline and wherein each unit includes between about 0.1 mg to 10 mg or said polypeptide.

Claims 41-53 (canceled).

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Claim 54. (previously presented) The polypeptide of claim 1 not fused or conjugated to an adjuvant polypeptide.

Claim 55. (previously presented) A protein containing composition comprising the polypeptide of claim 1 mixed in a protein containing plant cell extract.

Claim 56. (currently amended) The ~~vaccine~~ composition of claim 29, wherein an adjuvant is not present.

Claim 57. (previously presented) The protein containing composition of claim 55 wherein the plant cell extract is plant interstitial fluid.